

REMARKS

Responsive to the Office Action mailed September 26, 2005 and with an extension of time of three months, the present paper is timely filed on or before 27 March 2006, the first day after Sunday, 26 March 2006 that is not a Saturday, Sunday, or legal holiday in the District of Columbia.

By the present amendments, claims 1 and 4 are amended and claims 2 and 3 are cancelled. Accordingly, claims 1 and 4 – 19 are in the Application. Entry of the amendments and reconsideration of the Application are respectfully requested.

The Claim Amendments

Claim 1 is amended to recite that the humid gas is air and to recite an express numerical limitation to the RH of the air.

Claim 4 is amended to correct its dependency required by cancellation of claim 2 and 3.

Applicants respectfully submit that support for the amendments can be found, for example, in the claims as filed. Applicants respectfully submit that the claims do not introduce new matter into the Application.

Claim Rejections Under 35 U.S.C. § 112, paragraph second

Claims 6 – 8 were rejected under 35 U.S.C. § 112, ¶2 as allegedly indefinite. Because Applicants' claims 6 – 8 reasonably apprise the skilled artisan of the meets and bounds of that which Applicants consider to be their invention, Applicants respectfully traverse.

Claims are not construed in a vacuum. Rather, they are to be construed in light of the specification of which they are part. Accordingly, Applicants respectfully draw the Office's attention to at least page 4, line 29, to page 5, line 6 of their specification where Applicants succinctly describe "static" and "dynamic" contacting.

Because the skilled artisan reading claims 6 – 8 and having recourse to Applicants' specification would be well aware of the meets and bounds of Applicants' claims, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1 – 19 were rejected as allegedly obvious over Bogdan Mudryk et al., United States patent 5,981,751 (hereafter Mudryk et al.). Because the skilled artisan would not have a reasonable expectation that the method disclosed in Mudryk et al. could be successfully applied to removing residual alcohol from valacyclovir hydrochloride and further because Mudryk et al. neither teaches nor suggests all of the limitations of Applicants claims, Applicants respectfully traverse.

Mudryk et al. discloses a method purported to be useful for removing residual organic solvents from, e.g. pharmaceutical drug substances. The method is characterized in that the bulk substance is dried [sic] in the presence of water vapor. This is a sweeping general statement. But *only two* pharmaceutical drug substances are expressly discussed by Mudryk et al.: hydrocodone bitartrate and oxycodone hydrochloride.

Applicants respectfully submit that the method disclosed by Mudryk et al. is not instantly and unquestionably recognized as a technique of general applicability as, for example, distillation (in the case of a liquid) or recrystallization (in the case of a crystalline solid) might be. For example, some pharmaceutical drug substances might deliquesce. In other pharmaceutical drug solids the solvent might be bound in the crystal lattice (pseudopolymorph) and the water vapor might or might not have sufficient energy to displace the solvent from the crystal lattice. Applicants respectfully submit that the skilled artisan of the day would have considered the method disclosed by Mudryk et al. to be unpredictable, especially in view of the paucity of guidance in Mudryk et al.

Applicants respectfully submit that the sweeping generalizations in which Mudryk et al. teaches the process therein disclosed, the fact that the method was not recognized as one of general applicability, and the lack of predictability (especially if pseudopolymorphs were involved) preclude the requisite reasonable expectation of success. For this reason alone, Applicants respectfully submit that the rejection of claim 1 and 4 – 19 is improper and should be withdrawn.

In one embodiment, the vacuum hydration method, the method of Mudryk et al. requires an atmosphere *saturated* with water vapor. But in another embodiment that uses a fluidized bed apparatus, the atmosphere – nitrogen – is merely moist. Applicants respectfully the differences between air and nitrogen are not trivial (support of combustion, oxidation, and

indeed life) Clearly, Mudryk et al. neither teaches nor suggests the specific chemical and numerical limitations of Applicants' claims 1, and 4 -19. For this additional reason, Applicants respectfully submit that the rejection should be withdrawn.

Conclusion

Applicants respectfully submit that, based on the foregoing amendments and remarks, the claims are now in condition for allowance, which allowance is earnestly solicited. If, in the view of the Examiner, a telephone conference would advance prosecution of the Application, the Examiner is invited to telephone the undersigned attorney.

REQUEST FOR EXTENSION OF TIME


Applicants hereby petition under 37 C.F.R. § 1.136 for an extension of time to reply of THREE MONTHS for which a fee of \$ 1,020.00 is due under 37 C.F.R. § 1.17(a).

AUTHORIZATION TO DEBIT DEPOSIT ACCOUNT

The Commissioner is hereby authorized to debit deposit account 11-0600 in the amount of \$ 1,020.00 for the extension fee due herewith under 37 C.F.R. § 1.17(a). Applicants respectfully submit that no additional fee is due with this paper. If an additional fee is due, the Commissioner is hereby authorized to debit deposit account 11-0600 in the amount of such fee.

Dated: March 27, 2006

Respectfully submitted,


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